GUIDELINES FOR USE OF BOTOX FOR CHILDREN WITH SPASTICITY

Basic Requirements:

1. The decision to use Botox treatment will, in all cases, be a team decision, the result of collaboration among appropriate team members and the family. The team will include appropriate physician(s), i.e. orthopedics, neurology or neurosurgery and therapists, OT/PT.
2. All Botox treatment will be guided by a formal treatment plan. The treatment plan and any subsequent changes to the plan will be reviewed by the team.
3. All children receiving Botox treatment will undergo pre and post treatment evaluations of physical status (i.e. ROM, spasticity, pain) and function (i.e. gait, activities of daily living).
4. All children will receive physical or occupational therapy following Botox injection.
5. Patients will receive Botox injections no more frequently than once every three months.
6. Overall, Botox injection dosage will not exceed 20 units per kg.
7. Children under 18 months of age will be considered candidates for Botox treatment only after review by the medical directors.
8. A witnessed Consent to Treat form will be signed by the patient's parent/legal guardian.

Patient Selection Criteria/Prerequisites:

1. Child must have documented increased muscle tone which clearly puts him/her at risk for joint deformity and which causes one or more of the following:
   a. Pain
   b. Interference with <u>one or more</u> of the following functions:
      i. Proper positioning
      ii. Standing
      iii. Gait
      iv. Patient ability to perform activities of daily living
      v. Caregiver ability to maintain hygiene, care, or positioning

      OR
2. To provide diagnostic information regarding probable outcome of surgical treatment of targeted muscle group(s).
3. There must be documentation that less invasive approaches to spasticity management (i.e. serial casting, night splinting, a reasonable course of physical or occupational therapy, oral medication) have not adequately reduced the influence of spasticity on function during the previous 12 months and that the relative merits of surgical intervention have been considered.
4. Patient must be receiving ongoing medical/habilitative management through CRS and have been evaluated in a related clinic within the previous three months.
5. It must be clear that there are no psycho-social contraindications (i.e. poor attendance to medical or therapy appointments, family instability, lack of access to reliable transportation for follow-up care) in the recent patient/family history.

Request-Approval Process:

The Team (see 1. under Basic Requirements above) should approve all Botox therapy and should have evidence of the following:

1. Evidence that the patient meets III.A. and/or III.B and III.C. through E., above.
2. Documentation that the child's candidacy for Botox treatment has been discussed in a staffing which includes all relevant team members. This team will include, at least, the managing neurologist and therapist.
3. Documentation of physical and/or occupational therapy evaluation within the previous three months to record pre-treatment status and function, as related to the goals of Botox injection. This evaluation will have included:
   a. Classification of deformity, established measures of ROM, spasticity and, if appropriate, pain.
   b. Measures of functional ability.
   c. Videotape of pre-treatment function.
4. Documentation that the family has been provided with balanced information on the mechanisms of Botox treatment as well as the minor discomfort and minimal side effects of the treatment. They must have been given reasonable expectations for outcomes, and have committed to all necessary pre and post injection assessment and therapy.
5. Information regarding previous treatment approaches (therapy, casting, splinting, bracing, etc.) and outcomes.
6. Treatment plan which includes:
   a. Functional and physical treatment goals, how and when they will be measured, and by whom.
   b. Target muscle (group) and planned dosage, as well as preliminary estimate of total number of future injections.
   c. Post-injection therapy treatment recommendations, including frequency of sessions.
   d. Time at which post-injection physical and functional evaluations will take place and when child will return to appropriate neurology, orthopedic, and/or multi-disciplinary clinics.

Treatment Outcome Assessment:

Evaluation of treatment outcomes will differ somewhat depending upon the individual outcome goals established as part of the child's treatment plan. In all cases, however, outcomes will be assessed in each of four areas:

1. Technical/Musculoskeletal Outcomes. Assessed by physicians and therapists.
   Examples:
   a. Increased ROM
   b. Tone reduction
   c. Pain reduction, if appropriate
   d. Increased tolerance for bracing or splinting
2. Functional Outcomes. Assessed by therapists.
   Examples:
   a. Improved speed or quality of gait
   b. Improved positioning for healthy posture and function
   c. Improved ability to transfer
   d. Increased ability to perform activities of daily living such as feeding, grooming, hygiene

e. Post treatment - video taping

3. Patient/Family Satisfaction. Assessed by therapist and/or social worker. Examples:
   a. Patient/family perception of disability change
   b. Increased ease of care
   c. Patient commitment to treatment plan
4. Cost Effectiveness. Assessed and estimated by Case Eligibility Review. Examples:
   a. Short-term costs of injection, pre and post-treatment medical and habilitative management.
   b. Estimates of possible long-term cost-savings related to delay or prevention of contractures, deferred surgery, etc.

References:

Botulinum Toxin for Spasticity in Children with Cerebral Palsy: A Comprehensive Evaluation. Kristie Bjornson, PhD, PT[a]. Ross Hays, MD[b], Cathy Graubert, PT[a], Robert Price, MS[b], Francine Won, PT[a], John F. McLaughlin, MD[c], Morty Cohen, RPh[a]. PEDIATRICS Volume 120, Number 1, July 2007.

BTX-A. Pediatric Dosing Guidelines Management of Spasticity with Botulinum Toxin Type A (Botox), August 2005, www.mdvu.org/library/dosingtables/btxa.